epic T SERIES

User Manual

EPIC T User Manual P/N 5400478 Rev A

BIOLASE®

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INTRODUCTION

The Epic™ T-Series diode laser is a therapeutic device at the cutting edge of technology for use in providing temporary relief of minor pain.

The Epic T-Series utilizes a solid state diode as a semiconductor source for invisible infrared radiation. The energy is delivered to the treatment site via flexible fiber connected at one end to the laser source and the other end to the handpiece. The device is activated by means of a wireless footswitch.

This is a prescription device that is indicated for professional use only by licensed medical practitioners. The use of this device requires proper clinical and technical training. This manual provides instructions for those professionals that have completed the appropriate training.

When used and maintained properly, the Epic T-Series will prove a valuable addition to your practice. Please contact BIOLASE Customer Service at 1-800-321-6717 for any service needs. If you are located outside the USA, please contact your BIOLASE-authorized distributor.

1.PACKAGING

1.1 SYSTEM PARTS LIST

The Epic T-Series laser system includes the following:

1. Laser console (lithium ion battery pack already installed)
2. Screen Protectors (Peel-off clear screen cover - qty. 30)
3. Delivery System (installed)
4. Deep Tissue Handpiece (1) (shipped separately)
5. Three (3) pairs of protective laser eyewear (two (2) pairs of doctor safety glasses, one (1) pair of darker patient safety glasses)
6. DC power supply and power cord (one (1) for North America and one (1) for International)
7. Welcome Kit (Welcome Letter, Limited Warranty Information, User Manual)
8. Laser Warning Sign
9. Remote Interlock cable
10. Philips-head screwdriver (for installing Footswitch batteries)
11. Footswitch
12. AAA batteries (2)

NOTE: The laser ships with the lithium ion battery pack already installed.

NOTE: Use proper care when transporting the unit. Refer to Section 8 in this User Manual for instructions.

WARNING: No modification of this equipment is allowed.

1.2 FACILITY REQUIREMENTS

Electrical Supply (100-240V ~):

- 1.5A, 50/60Hz

Environmental Requirements:

- Temperature: 20-25 ºC
- Humidity: 15-95%, Non-condensing

2. EQUIPMENT DESCRIPTION

2.1 GENERAL

The EPIC T-Series system consists of three components:

- Laser console

- Delivery System

- Wireless Footswitch

2.2 LASER CONSOLE

The Console has a Display Panel (Touch Screen and Control Button) in front. It can be powered by an external mains power supply or an internal replaceable lithium ion battery pack, 14.4V, 2.9 Ah.

2.3 CONTROL PANEL

ITEM	ITEM DESCRIPTION
CONTROL Button	Activates the controls and display; places the unit into STANDBY or READY mode.
LED Indicator	• *Amber* indicates unit is in STANDBY mode. • *Green* indicates unit is in READY mode. • Blinking *green* indicates the emission of laser power. • Blinking *blue* indicates pairing between the footswitch and laser console is active

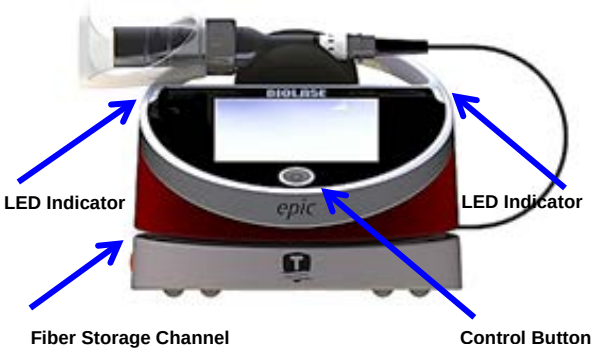


Figure 2.1: Control Panel (Front View)

2.4 DELIVERY SYSTEM

The Epic T-Series Delivery System consists of:

- Re-useable Fiber Optic Assembly
- Re-useable Deep-Tissue Handpiece (Figure 2.4)

NOTE: The fiber optic cable is detachable from the console. The handpiece is a re-usable accessory and will require disinfection prior to each patient treatment.

2.5 FIBER OPTIC CONNECTION

CAUTION: Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off.

The Epic T-Series ships with the fiber optic cable already attached.

To disconnect the fiber optic cable from the laser console, **make sure the laser console is turned off and the cable is completely unwound from the console base**, grab the fiber optic access plug and slowly pull it straight back from the optical access port (Figure 2.3).

To re-install the fiber optic cable, **make sure the laser console is turned off**. The fiber optic cable is attached to the console by inserting the optical access plug (Figure 2.2) into the optical access port (Figure 2.3).

NOTE: You should hear the fiber optic "click" into place; if you do not hear it "click," remove the fiber optic and reinstall it.

For storage, wind the cable in the fiber storage channel around the base of the console in a counterclockwise direction (Figure 2.1).

CAUTION: Do not bend the fiber optic at a sharp angle, as it is can break. Make sure it is not caught or pinched between the housing and the fiber optic access plug.

Figure 2.2: Fiber Optic Access Plug

Figure 2.3: Optical Access Port

2.6 DEEP TISSUE HANDPIECE

NOTE:

The Deep Tissue Handpiece is reusable and equipped with a disposable single-use protective shield. The handpiece requires disinfection before and after each patient treatment. **This handpiece cannot be sterilized in the autoclave.** For instructions on disinfecting the handpiece, refer to section 8.

It is recommended to wipe the disposable shield with alcohol prior to use. The disposable shield is for single-use only to avoid cross-contamination. Dispose of when treatment session is completed.

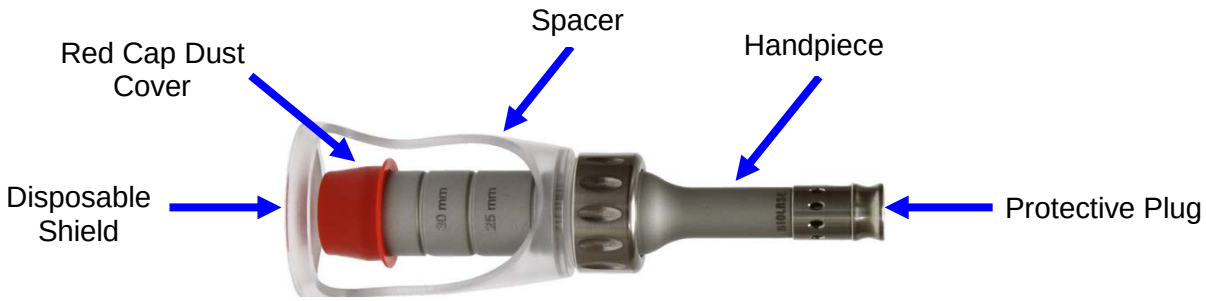


Figure 2.4: Deep Tissue Handpiece

- Remove Red Cap Dust Cover and Protective Plug from the Deep Tissue Handpiece.
- Slide the handpiece over the shaft until it clicks into place (Figure 2.5).

Figure 2.5

- Place the protective shield over the adjustable spacer (Figure 2.6).

Figure 2.6

- Loosen the Lock Ring and set the Spacer at the desired spot size Detent Location (Figure 2.7). Tighten the Lock Ring.

Figure 2.7

The handpiece is now ready to use.

To remove the handpiece, press and hold the buttons on the side of the fiber shaft and pull the handpiece away from the shaft.

3. SAFETY

3.1 PRECAUTIONS

Failure to comply with precautions and warnings described in this User Manual may lead to exposure to dangerous optical radiation sources. Please comply with all safety instructions and warnings.

3.2 SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

- When the laser is in use, all operatory entrances must be marked with an appropriate warning sign (one (1) included).

- Do not operate in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before laser is used. Attention should also be drawn to the danger of ignition of endogenous gases.
- All persons present in the operatory must wear protective laser eyewear.

NOTE: For replacement or additional protective laser eyewear, please contact BIOLASE.

CAUTION: Periodically inspect laser eyewear for pitting and cracking.

LASER WARNING: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

WARNING: Do not use this unit if you suspect it of functioning improperly or other than described herein.

CAUTION: This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate the interference.

CAUTION: Always ensure that the proper laser parameters are set before the EPIC T-Series laser is used in a clinical setting.

LASER WARNING: Always ensure that the protective laser eyewear is appropriate for the laser wavelength.

- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam at a person's eyes.
- Always place the system into STANDBY mode (by pressing the Control Button while in READY mode) before exchanging handpieces.
- Toggle the ON/OFF switch (located on the rear of the console) to the OFF (O) position before leaving unit unattended.

LASER WARNING: Do not open unit housing at any time. Danger from optical radiation may exist.

LASER WARNING: Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. If aimed directly at these surfaces the laser beam will reflect and create a potential hazard.

3.3 SAFETY FEATURES

Energy Monitor

The energy monitor measures and verifies power output. Power deviations of more than ± 20% from the selected value will cause the display to show the error message: "LASER CURRENT HIGH/LOW".

The laser console will not operate until the system first clears the error and then goes into READY mode. If the error message persists, please contact BIOLASE Service at 1-800-321-6717.

System Monitor

The system monitors the emergency stop switch, remote key, wireless footswitch connection, and output power. An error in any one of these will stop the system. The text display will indicate the type of error. Operation will not resume until the error is cleared.

Power Switch

The laser console can be switched ON (I) or OFF (O) using the Power Switch on the back of the console.

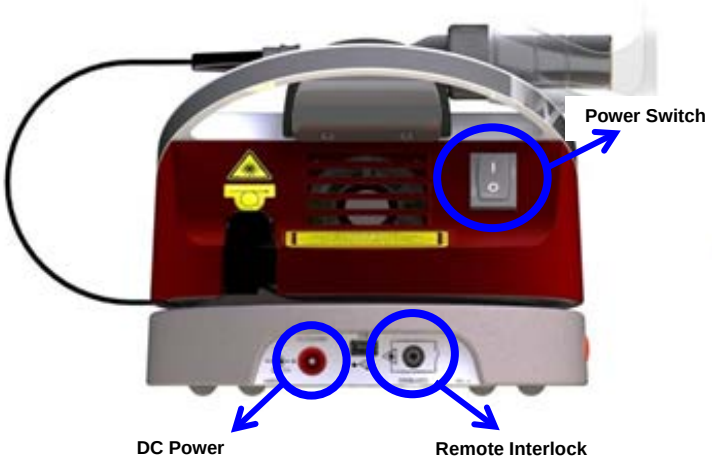


Figure 3.1: Power Switch, DC Power Input, Remote Interlock

Figure 3.2: Power Supply Module with cord

CAUTION:	Use only the Power Supply Module supplied with the EPIC T-Series laser system (BIOLASE Part Number 2400129).

Access Key Code

The Access Key Code prevents unauthorized use of the system. It is activated every time the system is turned on with the Power Switch (refer to Section 4 for code).

NOTE:	Placing the laser in sleep mode by pressing and holding the Control button on the front panel does not re-set the Access Key Code. Turn the Power Switch OFF (O) only when the system will not be in use for a long period of time.

Control Button

Once the power switch is set to the ON (I) position, enter the access key code. After setting the desired parameters for a procedure, press the CONTROL button on the control panel to enter into READY mode. The aiming beam will illuminate to indicate that the system is ready for use.

Wireless Footswitch

The Epic T-Series will not emit laser energy until the user presses down on the footswitch while the laser is in READY mode. The footswitch is designed to work using wireless technology.

Two (2) AAA batteries are required to power the footswitch (included). For instructions on how to replace the footswitch batteries, see Section 8.

The footswitch is protected by a metal cover. To access, first press down on the cover to unlatch it. Now the footswitch can be pressed to fire the laser.

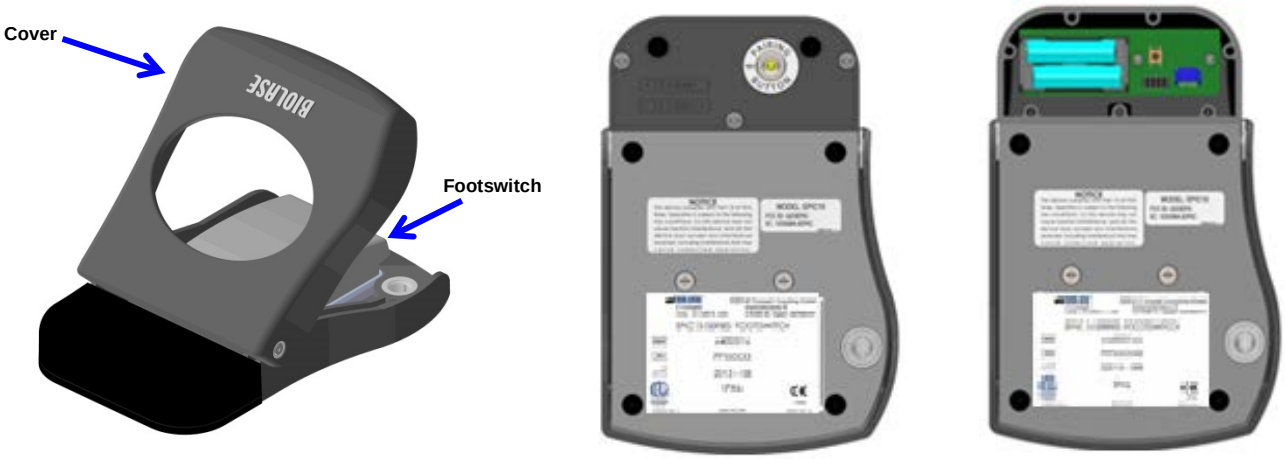


Figure 3.3: Footswitch Assembly

Remote Interlock

This feature allows the laser console to be connected to the remote sensor, preventing its operation when triggered (*e.g.*, by opening door). The electric cable from this connector should be wired to the normally closed switch, sensing the opening of a door and turning the laser console off when the switch is open.

To override this feature, don't connect the plug.

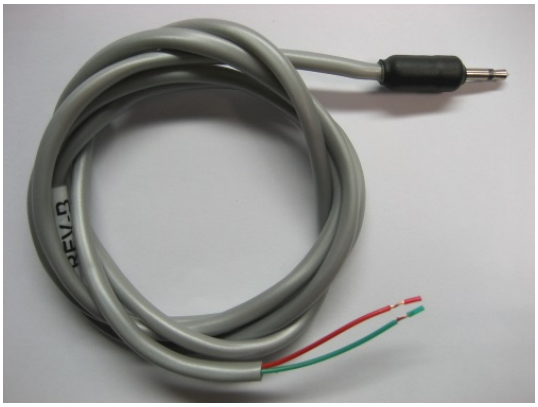


Figure 3.4: Remote Interlock Connector

Emergency Stop

Press the red Emergency Laser Stop button to instantly turn off the laser console. The error screen will display an “Emergency Switch Error” message and the amber LED will begin flashing. To clear the error, press the Emergency Laser Stop button again; in 2 to 5 seconds the amber LED will stop flashing and the system will automatically go into STANDBY mode.

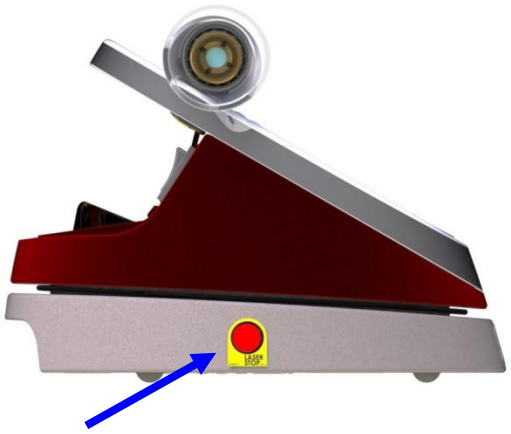


Figure 3.5: Emergency Laser Stop (Left Profile View)

Functional Display

The System Color Display with Touch Screen and LED indicators on the control panel show the functional conditions of the system.

3.4 SAFETY CLASSIFICATION

The following safety classifications are applicable to the device:

- Laser Radiation – Class 4
- Aiming Beam – Class 1
- Type of protections against electrical shock – Class 1
- Degree of protection against electrical shock – Type B Applied Part
- Not protected against water ingress – Ordinary Equipment
- Not suitable for use in presence of flammable anesthetic mixture
- Operation Mode – Continuous Wave
- Wireless Footswitch – IPX6

4. OPERATION INSTRUCTIONS

4.1 SYSTEM SETUP

- Place the unit in a clean, dry, and well-ventilated area.
- Verify power switch is in the OFF (O) position.
- Epic T-Series will work using either DC power or the rechargeable battery pack:
  - *DC Power*: Connect the power cord of the power supply to the laser console and plug into a wall outlet
  - *Rechargeable Battery*: The EPIC T-Series is shipped with the battery pack already installed; to charge the battery pack, connect the power cord of the DC power supply to the laser console and plug into a wall outlet. Before first use, fully charge the battery (at least 3 hours). Once the battery is charged, unplug the power cord from the wall outlet and the laser console. The laser console will run on battery power alone.

The system ships from the factory with the fiber already connected to the laser console

NOTE: To fully charge the battery, plug the power supply in and then turn the laser console ON (I) at the Power Switch. The laser console will start to charge and the unit will go into sleep mode (with the screen off) after 5 minutes; if the power supply is plugged in but turned OFF (O) at the Power Switch, the battery will still charge, but at a slower rate

CAUTION: Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off.

CAUTION: Do not cover or block ventilation channels. These channels provide an air-flow path to cool the unit.

CAUTION: Do not bend the fiber optic cable at a sharp angle, as it is can break. Make sure it is not caught or pinched between the housing and the fiber optic access plug.

- Remove protective cap from the end of the fiber shaft.
- Carefully connect the handpiece to the fiber optic assembly (Figure 2.5).
- Wind any excess fiber optic cable onto the fiber spool counterclockwise in the fiber storage channel around the base of the console (Figure 2.1).
- The handpiece is now ready to use. To store the handpiece, place it in the handpiece holder located at the top of the laser console.

LASER WARNING: Never point the laser at a person's eyes.

LASER WARNING: Never operate the laser without a handpiece attached.

LASER WARNING: All persons present in the operatory must wear protective eyewear when the laser is in use.

4.2 OPERATION - TURN ON THE EPIC T-SERIES LASER

- Ensure that the battery has enough charge for operation, or connect the power supply cord to the power connector on the laser console and plug the cord into a wall outlet.
- Turn the Power Switch at the rear of the console to the ON (I) position. The "BIOLASE" logo screen will appear (Figure 4.1). After three (3) seconds the EPIC T-Series "Welcome" screen will be displayed (Figure 4.2).

Figure 4.1

Figure 4.2

Figure 4.3

- Enter the three digit access code using the touch screen. The Access Key Code is **888**. (If the incorrect code is entered, an '**X**' appears briefly in the window (Figure 4.3); press the '**X**' or wait 3 seconds to revert back to the Welcome screen; re-enter the correct code.
- The system will go to the HOME screen.

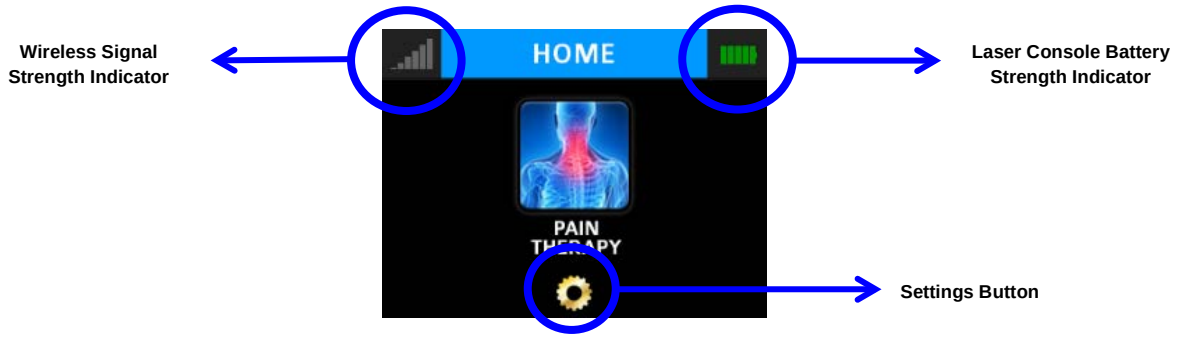
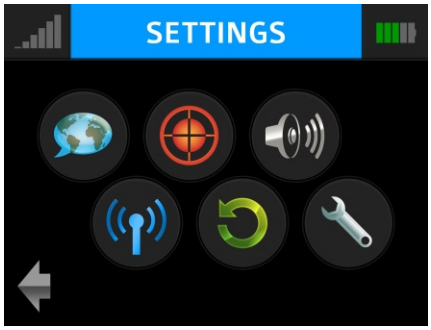


Figure 4.4: Home Screen

4.3 SETTINGS SCREEN

Pressing the Settings button on the HOME screen accesses the Settings screen; this screen allows the user to make changes to several system settings:



- Language Selection
- Aiming Beam (5 levels of brightness adjustment)
- Volume (5 levels of sound adjustment)
- Service Mode (accessible only by authorized BIOLASE Service Representatives)
- Restore to Factory Default Settings
- Wireless Menu - Access to Pairing Screens

Figure 4.5

4.4 PAIRING THE FOOTSWITCH TO THE LASER CONSOLE

Verify that the footswitch and laser console are paired; a blue LED indicator light on the laser console will blink when pairing is established. The laser and footswitch are shipped already paired. However, if pairing is not confirmed, an "" will appear in the pairing icon located in the upper left hand corner of the touchscreen (Figure 4.6).

Figure 4.6

To re-establish pairing, take the following steps:

1. Go to the Settings menu on the laser console display by pressing the Settings button and select the "Wireless" icon .

Figure 4.7

2. A screen will appear indicating that pairing of the footswitch to the laser console has been lost (Figure 4.7); press the green PAIR button. PAIR

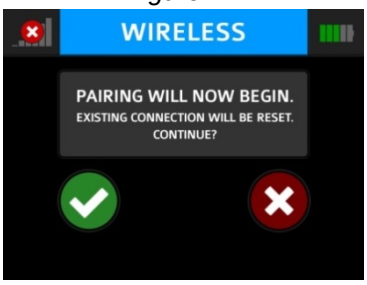


Figure 4.8

3. The message that "PAIRING WILL NOW BEGIN" will appear; press the green check mark to continue (Figure 4.8).

Figure 4.9

4. To complete the pairing process, turn the footswitch over and press the Pairing Button for four (4) seconds (Figure 4.9).

`

5a. The Wireless screen will appear indicating that pairing was successful and that the footswitch and laser console are now paired (Figure 4.10).

Proceed to step 6.

Figure 4.10

5b. If pairing has not occurred, the Wireless screen will appear again indicating that pairing was not successful (Figure 4.11); press the green button to repeat steps 3 – 5a.

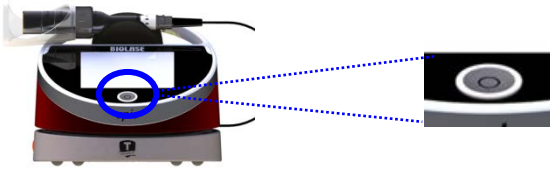
Figure 4.11

6. Press the Settings button to return to the Settings menu; press the arrow on the bottom left of the Settings screen to return to the Home screen (Figure 4.12).

Figure 4.12

4.5 CONTROL BUTTON

The CONTROL button on the front of the laser console is a multi-functional button (Figure 2.1). Pressing and holding the Control Button for approximately two (2) seconds will allow the transition from STANDBY or READY mode to SLEEP mode. Note that you will not be allowed to go into READY mode unless you have chosen a treatment module on the HOME screen first.



4.6 ENTERING READY OR STANDBY MODES

Press and release the Control Button to place the laser console into either READY or STANDBY mode. The laser console will only emit laser energy when the footswitch is pressed and the laser console is set to READY mode. While in READY or STANDBY mode, mode setting and/or power setting values may be changed only when the laser is not firing. If the

laser is firing (*i.e.*, the footswitch is engaged), the ability to change the settings is blocked. ("READY" or "STANDBY" is displayed in the lower right hand corner of the display screen).

4.7 READY MODE

When entering READY mode, the laser console fan will turn on and pressing the footswitch will activate laser radiation. There is a delay of two (2) seconds between switching to READY mode and the ability of the laser console to emit a laser beam.

NOTE:	The aiming beam is on only when the laser is in READY mode or when adjusting the brightness of the beam while in Settings mode. If the aiming beam is not visible in either instance, remove the handpiece and confirm the beam is actually on by shining the end of the trunk fiber on a plain, non-reflective surface. **DO NOT** look directly at the output end of the trunk fiber. If the aiming beam is not on, turn off the laser console, then remove and re-install the trunk fiber (see Section 2.6). If the aiming beam is still not on, turn off the laser console and call Biolase Service.

4.8 WIRELESS FOOTSWITCH

The wireless footswitch is powered by two (2) AAA batteries.

When the wireless footswitch is pressed in READY mode and the laser fires, a beeping sound indicates that laser energy is present. A green LED will begin flashing and a blue LED will light at the top corners of the laser console, confirming the footswitch and laser are paired.

In the top left corner of most screens is a Signal Strength Indicator which displays the signal strength between the laser console and the footswitch (strongest is five (5) bars). Pressing and releasing the footswitch while in Standby mode will update this indicator. Although the unit will work with a signal level as low as one (1) bar, a weaker signal level will make the connection between the footswitch and laser console more vulnerable to wireless (RF) interference from other sources, such as cell phones or microwaves. To improve the signal strength, reposition either the footswitch or the laser console until the signal indicator achieves the strongest possible level for optimal operation.

NOTE:	When the footswitch is not in use, it will go into SLEEP mode to conserve battery power. It automatically reactivates when it is pressed.

4.11 USING THE EPIC T-SERIES TOUCH SCREEN DISPLAY

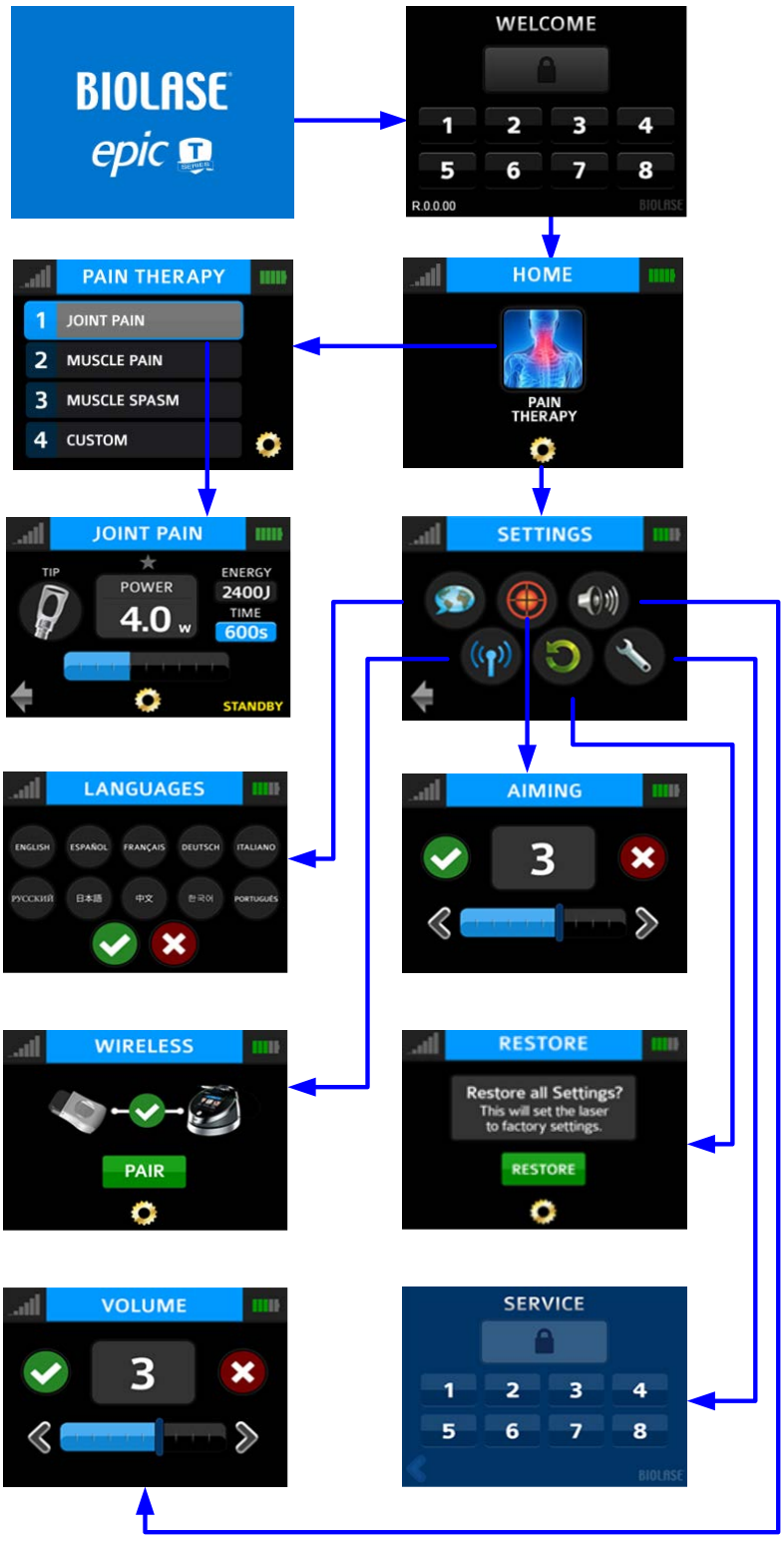


Figure 4.13

4.14 TURN THE LASER CONSOLE OFF

- Wind the fiber cable onto the fiber spool counterclockwise around the base of the console.
- Place the handpiece onto the handpiece holder.

CAUTION: Verify that the fiber optic tubing assembly is not twisted once the handpiece is returned to the holder. The fiber may break if it is twisted.

- Press the CONTROL button on the front of the console for more than 2 seconds to turn the display off.
- Press the Power Switch at the rear of the laser console to the OFF (O) position if the laser system will not be used for a long period of time.

5. SPECIFICATIONS

5.1 GENERAL

Dimensions	5.7 in (W) x 4.4 in (H) x 6.5 in (L) (14.5 cm x 11.2 cm x 16.5 cm)
Weight	2.75 lbs / 1.25 kg

5.2 ELECTRICAL

Operating Voltage	100V - 240V ~ at 1.5A
Frequency	50/60Hz
External Fuses	None
Main Control	Power Switch
Remote Interruption	Remote Interlock
Disable Control	Emergency Stop Button
Battery	Lithium Ion Rechargeable, 14.4V, 2.9Ah
DC Power Supply Module	12V DC, 5A

5.3 LASER

Laser Classification	IV (4)
Medium	InGaAsP Semiconductor diode
Wavelength	940 ± 10nm
Max Power Output	10W
Power Accuracy	± 20%
Power Modes	Continuous
Spot size Deep Tissue Handpiece	30 mm diameter = 7.1 cm^2 area

Nominal Ocular Hazard Distance (NOHD)	4.77 meters
Beam Divergence	8 - 22° per side angle
Standard Fiber Cable Length	6.8 feet (2 meters)

5.4 OTHER LIGHT SOURCES

Aiming Beam	Laser diode, max 1 mW, 625 nm – 670 nm, Class 1

6. CONTRAINDICATIONS, WARNINGS & PRECAUTIONS

6.1 CONTRAINDICATIONS

All clinical procedures performed with Epic T-Series must be subjected to the same clinical judgment and care used with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease (including pacemakers), lung disease, bleeding disorders, sleep apnea or an immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

6.2 WARNINGS AND PRECAUTIONS

Prescription Statement

Federal Law restricts this device to sale by or on the order of a physician or other licensed medical practitioner.

Eyewear

Doctor, patient, assistant and all others inside the operatory must wear appropriate laser eyewear protection for the diode laser wavelength of 940 ± 10nm.

Training

Only licensed professionals who have reviewed and understood this User Manual should use this device. BIOLASE assumes no responsibility for parameters, techniques, methods, or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc.

LASER WARNING: Never point the laser at a person's eyes. All persons present in the operatory must wear protective eyewear when the laser is in operation.

7. CLINICAL APPLICATIONS

7.1 INTRODUCTION

Please review this section carefully before using this device in a clinical situation.

7.2 INDICATIONS FOR USE

The Epic T-Series is intended for topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

7.3 PAIN THERAPY

The Epic T-Series diode laser is designed to provide near-infrared laser energy to a tissue surface for the purpose of temporary pain relief when applied with the Deep Tissue Handpiece. The pain therapy procedure is the process by which tissue temperature is elevated for the temporary relief of minor pain, the temporary increase in local blood circulation, and the temporary relaxation of muscle, as stated in the Indications for Use.

Affected muscles and/or joints have to be exposed to an adequate level of therapeutic energy over a short period of time to provide effective therapeutic effects. Some patients may require more than one laser application or a series of treatments before significant improvement is reported. Repeat the therapy as necessary and monitor the progress of the patient's condition throughout the treatment.

Refer to the Fitzpatrick Skin Type Scale (Figure 7.1) when performing pain therapy procedures. The diode wavelength has increased absorption in melanin in the skin, causing greater heating of the skin surface of patients with a higher melanin concentration (darker skin types).

Patients with higher melanin content in their skin may feel more discomfort during treatment, which may be alleviated by moving the handpiece, defocusing the energy, or decreasing the power setting.

Fitzpatrick Skin Type Scale	
TYPE I	Highly sensitive, always burns, never tans. Example: Red hair with freckles
TYPE II	Very sun-sensitive, burns easily, tans minimally. Example: Fair-skinned, fair-haired Caucasians
TYPE III	Sun-sensitive skin, sometimes burns, slowly tans to light brown. Example: Darker Caucasians
TYPE IV	Minimally sun-sensitive, burns minimally, always tans to moderate brown. Example: Mediterranean-type Caucasians
TYPE V	Sun-insensitive skin, rarely burns, tans well. Example: Some Hispanics, some Blacks
TYPE VI	Sun-insensitive, never burns, deeply pigmented. Example: Darker Blacks

Figure 7.1

Pre-programmed Pain Therapy Settings

To access the pre-programmed procedure values:

1. Go to the Procedures menu by pressing the Pain Therapy icon on the Home screen.
2. Press the button associated with the type of condition requiring treatment.

CAUTION: Always use clinical judgment when selecting power to ensure optimal clinical results. Observe the clinical effects on the treatment area at all times and adjust settings parameters accordingly.

To store your personal preferred settings for any procedure:

A. Follow steps 1 and 2 above.

B. Enter the new values.

C. Touch and hold the condition name for more than 2 seconds; you will hear a beeping sound confirming the settings are saved.

NOTE: The pain therapy pre-sets installed at the factory are based on clinical recommendations and feedback from experienced laser medical practitioners.

7.7 TABLE OF PRE-PROGRAMMED PAIN THERAPY SETTINGS

PROCEDURE NAME	MODE	SETTING	TIME (SECONDS)	ENERGY (J)	SPACER
JOINT PAIN	CW (Continuous)	4 W	600	2400	30 mm
MUSCLE PAIN	CW (Continuous)	4 W	300	1200	30 mm
MUSCLE SPASM	CW (Continuous)	4 W	300	1200	30 mm
CUSTOM	CW (Continuous)	4 W	60	240	30 mm

Figure 7.10

Pain Therapy – Adverse Effects

Some reddening of the skin at the treatment site is normal due to increased circulation; however, in very rare cases burning or blistering of the skin may occur. **Immediately stop treatment**, rinse the area with cool water or place a cold pack to the affected area for at least 5 minutes, then apply a burn ointment or spray. **DO NOT USE ICE.**

Patients should be monitored for discomfort and visual skin changes. Redness has been associated with increased temperature at the site of application and increased absorption properties of the skin. If discomfort or redness of the skin occurs at any time during the treatment, you have the following options:

- Move the handpiece relative to the affected anatomy
- Defocus the energy by moving the handpiece further away from the skin
- Decrease the power setting
- Stop treatment

Pain Therapy – Warnings and Precautions

- Scar tissue has been associated with poor circulation and reduced cooling through heat transport by blood; power settings may have to be reduced to avoid overheating.
- Patients with tender or sensitive skin may be hypersensitive to heat; reduce power as necessary to ensure comfort during treatment.
- Patients with swelling and/or inflammation may be sensitive to heat; reduce power as necessary to ensure comfort during treatment.
- Do not treat open wounds.

- Muscle tissue closer to the skin surface may experience a higher absorption of heat; carefully monitor skin temperature and reduce power as necessary.
- Excessive fatty tissue is known to transmit heat without much attenuation; reduce power.
- Different implant materials will respond differently to laser energy and heat; be aware of any implants and their location; avoid direct exposure to laser energy or heat at the site of the implant.
- Avoid treatment of sites that have tattoos.
- Do not apply ointment, creams, lotions or heating lotion patches at, or in close proximity to, the treatment area.
- Do not apply therapies prior to treatment that could change body temperature, such as ultrasound, ice/heat pack, electrical stimulation, or heating patches.
- Do not apply treatment over articles of clothing.

Recommended Use

There are four main variables that impact the safety and effectiveness of pain therapy procedures:

- Power output
- Distance from the skin surface
- Range of movement of the handpiece
- Patient skin type

Safety and effectiveness are described by elevating the skin temperature in the treatment area utilizing the setting recommended below. Use personal clinical judgment with consideration of the Fitzpatrick Skin Type Scale when selecting procedure parameters; monitor the patient and adjust the setting as necessary for effectiveness and patient comfort.

NOTE:	To avoid potential patient discomfort and/or skin damage, it is advisable to use a test spot prior to the initial treatment to assess the suitability of the selected settings for the individual patient.

Using the Deep Tissue Handpiece

If holding the handpiece in a constant location, the recommended initial power setting for therapeutic effect is 4.0W CW delivered over 10 minutes of continuous treatment, with the spacer set at a 30mm spot size. Always monitor patient response; adjust power and/or distance as needed for patient comfort.

8. MAINTENANCE

WARNING: No modification of this equipment is allowed.

8.1 DAILY MAINTENANCE

Use the peel-off clear covers for the laser console supplied with the system. Use disinfectant to wipe down the front panel and handpiece holder of the EPIC T-Series system after each procedure. **Do not use bleach or abrasive cleansers.**

8.2 CLEANING AND DISINFECTION PROCEDURES

- The handpiece is sold with clear, disposable protective shields. **It is reusable and must be disinfected between patients to avoid cross-contamination.**
- **The Deep Tissue Handpiece is not autoclavable.**
- The clear protective shields are intended for single use only to avoid cross-contamination and should never be re-used.
- To disinfect the Deep Tissue Handpiece, wipe the entire outer surface of the handpiece with cotton gauze and isopropyl alcohol.
- It is recommended to wipe the disposable shield with alcohol prior to use. **Dispose of after one-time use.**

8.3 INSTALLING/REPLACING THE CONSOLE BATTERY PACK

1. To install or replace the battery pack, remove the battery cover on the underside of the console using the Phillips screwdriver included with the laser system (Figure 8.1).
2. To remove the battery, grip the battery at the top and pull the cable away from the connector (Figure 8.2). Do not tug or wrench the cable from the connector.
3. To install the battery, insert the connector wire from the battery to the unit, making sure the red wire is on the left, and gently place the battery into the compartment (Figure 8.2).
4. Replace the battery cover on the bottom of the unit, using the Phillips screwdriver provided.
5. Connect the power cord of the DC power supply to the unit and plug into a wall outlet. Before first use, you should fully charge the battery (at least three (3) hours). Once the battery is charged, unplug the power cord from the wall outlet and the console. The unit will run on battery power alone. (see Section 4.1)
6. Recycle the used Lithium Ion battery as regulated. Do not throw it in a trash bin.

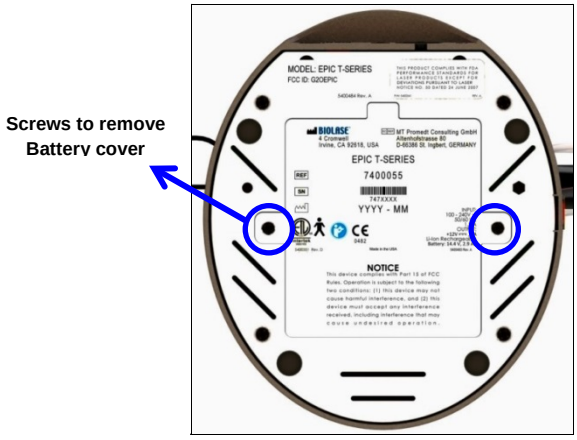


Figure 8.1: Battery Cover/Bottom of Console

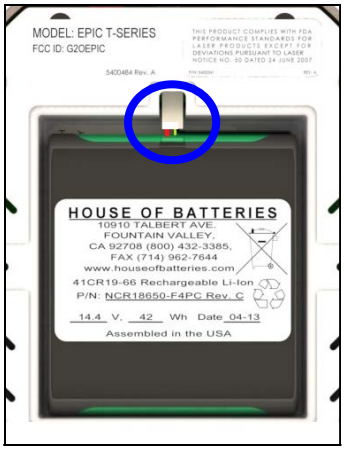


Figure 8.2: Battery Pack/Connector Wire

NOTE:	Only use the battery pack supplied by BIOLASE. The battery pack is a separate accessory (BIOLASE p/n 6400457).

8.4 CHANGING THE WIRELESS FOOTSWITCH BATTERIES

The wireless footswitch is powered by two AAA batteries. When the batteries are low, a warning message will appear on the touchscreen indicating that the batteries need to be replaced. To replace the batteries, unscrew the battery cover on the underside of the footswitch (Section 3), remove the old batteries, and install the new ones, replacing the cover when done. Dispose of the used batteries as regulated; do not throw them in a trash bin.

Do not press/push/touch the Pairing Button (Figure 8.3) while changing the batteries, as this will disrupt the pairing of the laser console and footswitch.

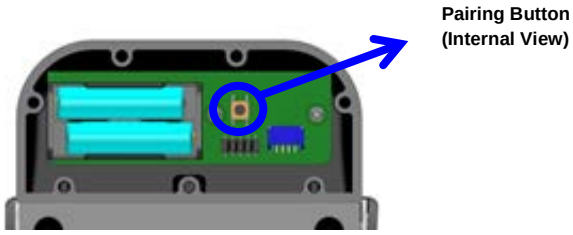


Figure 8.3

Replacing the batteries may disrupt the pairing of the laser console and footswitch. If you find the wireless communication has been interrupted, reestablish pairing by following the instructions provided in Section 4.

NOTE:	To ensure the longevity of the battery power, only BIOLASE-supplied batteries are recommended as replacements (BIOLASE p/n 6400463); these are industrial-grade batteries which under normal use have a longer life than conventional AAA batteries.

8.5 TRANSPORTATION

The Epic T-Series is susceptible to damage if not handled properly. The unit should ALWAYS be handled carefully and never banged, jarred, jolted, dropped, or knocked.

Do not transport the unit unless it is completely packaged inside its shipping box. If you have any questions regarding transportation please call BIOLASE Service at 1-800-321-6717.

8.6 STORAGE

The Epic T-Series should be stored in a cool, dry place when not in use. Storage temperature 15°C-35°C (59°F-95°F), relative humidity 10%-70%, non-condensing. Cover the unit when not in use for extended periods of time. Store the system in a place where it will not be accidentally bumped or banged.

CAUTION:	Make sure the distal end of the handpiece shaft is protected from dirt with the protective tip plug and handpiece.

CAUTION:	Remove the batteries from the footswitch if the EPIC T-Series is not likely to be used for some time.

The Epic T-Series is shipped inside a custom shipping box. Please save and store the box in a cool, dry place for use when transporting the laser, or for long-term storage.

9. CALIBRATION

9.1 CALIBRATION SCHEDULE

Calibration procedure is recommended to be performed every twenty-four (24) months in order to maintain the required accuracy of output power versus displayed power. Bi-annual calibrations can be performed at a certified depot repair facility. Call BIOLASE Service at 1-800-321-6717 or your Authorized Service Representative to schedule an appointment.

10. SOFTWARE SPECIFICATION

BIOLASE respects the intellectual property of others, and we ask our users to do the same. Epic T-Series software is protected by copyright and other intellectual property laws.

This product contains proprietary, copyrighted software developed by BIOLASE, Inc. All rights reserved in the USA and other countries.

11. TROUBLESHOOTING

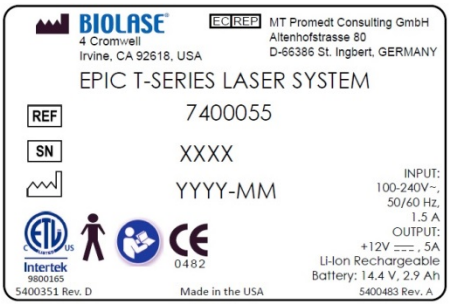
Should any of the on-screen messages listed in Figure 11.1 appear, follow the troubleshooting instructions for the specific message as noted below.

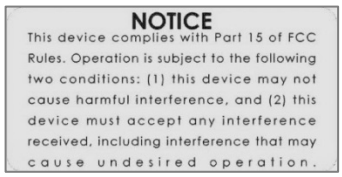
NOTE:	For any on-screen message not listed in Figure 11.1, re-power the laser console; if the message does not clear, call **BIOLASE Service at 1-800-321-6717** or your authorized Service Representative

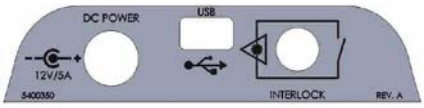
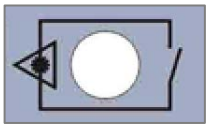
Title	Message !	Reason ?	Fix ✓
Error 1	Thermistor Open	Thermistor Open	Call BIOLASE Service
Error 2	Thermistor Shorted	Thermistor Shorted	
Error 3	Shutdown Temperature	System too hot	Allow 5-10 mins for laser to cool down
Error 4	Laser Current High/ Low	Output is out of specs	Call BIOLASE Service
Error 5	FS shorted in Standby	FS is partially pressed or is damaged	Press/Release FS or call Biolase Service
Error 6	ON/OFF button Stuck	Key stuck	Press Front key
Error 7	Flash Corrupted	Memory Corrupted	Call BIOLASE Service
Error 8	No Fiber	Fiber not inserted	Plug in Trunk Fiber
Error 9	Lost Footswitch Communication	Wireless Interference	Reposition console or FS to improve communication
Error 10	Emergency Switch	E-Switch Pressed	Press E-Switch Again
Error 11	Remote Interlock	Remote interlock open	Check Remote Interlock closed
Error 12	Battery Critically Low	Battery Critically Low	Plug in DC supply
Warning 1	Temp High	System is hot	Allow 5-10 mins for laser to cool down
Warning 2	Battery Low	Battery is low	Plug in DC supply
Warning 3	Battery Not Connected	Battery not connected	Plug in Battery
Warning 4	FS Battery Low	Battery on FS low	Replace FS battery
Alert 1	Wireless Not Paired	No wireless connect	Re-establish pairing (see Sec 4)
Alert 2	System must be in READY mode to lase	System is not in READY mode	Press the Control Button in any procedure screen

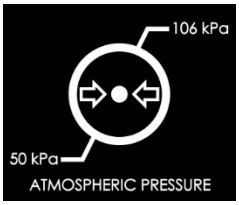
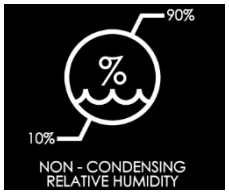
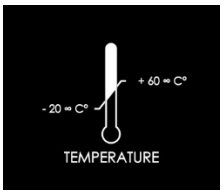
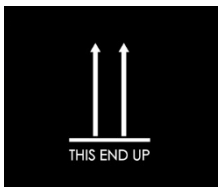
Figure 11.1

APPENDIX A – LABELING

Symbols	Description
	**Product ID Label** **Location:** Bottom of laser console
	Manufacturer
	Date of Manufacture
	Catalog/Part Number
	Product Serial Number
	Refer to User Manual
	Type B Applied Part: The applied part is not conductive to the patient.
	FDA Compliance Label: Indicates the device complies with FDA laser standards.

	Warning Label: Indicates there is the risk of possible exposure to both infrared and visible laser radiation. **Location:** Back of laser console
	FCC Label: Lists Federal Communication Commission registration number. **Location:** Bottom of Console
	FCC Label: Lists Federal Communication Commission registration number. **Location:** Bottom of Footswitch
	**FCC Compliance Notice:** The footswitch and laser console comply with Part 15 of FCC Rules regarding unlicensed transmissions. **Location:** Bottom of Footswitch
IPX6	**Ingress Protection Code:** The footswitch is water-resistant, protected against splashes of water.
	Laser Warning: Indicates the system contains a laser. **Location:** Back of Laser console
	Fiber Warning: Indicates the laser aperture is at the end of the fiber. **Location:** Back of Laser console

	Emergency Laser Stop Switch: The switch used in emergencies to stop laser output. **Location:** Right side of Laser console
	WEEE (Waste Electrical and Electronic) Recycle Lithium Ion battery as regulated. Do not throw in trash bin.
	**DC Power, USB, Remote Interlock Label:** Identifies input ports
	Power Input Rating: 12 Volts Direct Current, 5 amps
	Mini USB Input: For external programming
	**Remote Interlock:** Input for Remote Interlock Connector which, when applied to the access door of the operatory and activated, will shut off the laser.
	Prescription Statement: Federal Law restricts this device to sale by or on the order of a physician or other licensed medical practitioner.

	**Atmospheric Pressure Limitations**
	Fragile: Handle with care
	Keep Dry
	**Humidity Limitations**
	**Temperature Limitations**
	**This End UP**

APPENDIX B – SAFETY PRECAUTIONS FOR LITHIUM-ION BATTERY PACKS

When USING the BATTERY

WARNING

1. Misusing the battery may cause the battery to get hot, rupture, or ignite and cause serious injury. Be sure to follow the safety rules listed below:

    - Do not place the battery in fire or heat the battery.
    - Do not install the battery backwards so that the polarity is reversed.
    - Do not connect the positive terminal and the negative terminal of the battery to each other with any metal object (such as a wire).
    - Do not carry or store the batteries together with necklaces, hairpins, or other metal objects.
    - Do not pierce the battery with nails, strike the battery with a hammer, step on the battery, or otherwise subject it to strong impacts or shocks.
    - Do not solder directly onto the battery.
    - Do not expose the battery to water or salt water, or allow the battery to get wet.

2. Do not disassemble or modify the battery. The battery contains safety and protection devices which, if damaged, may cause the battery to generate heat, rupture, or ignite.
3. Do not place the battery on or near fires, stoves, or other high-temperature locations. Do not place the battery in direct sunshine or use or store the battery inside cars in hot weather. Doing so may cause the battery to generate heat, rupture, or ignite. Using the battery in this manner may also result in a loss of performance and a shortened life expectancy.

CAUTION

1. If the device is to be used by small children, the caregiver should explain the contents of the user's manual to the children. The caregiver should provide adequate supervision to ensure that the device is being used as explained in the user's manual.
2. When the battery is worn out, insulate the terminals with adhesive tape or similar materials before disposal.
3. Immediately discontinue use of the battery if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot, changes color, changes shape, or appears

abnormal in any other way. Contact your sales location or BIOLASE if any of these problems are observed.

4. Do not place the batteries in microwave ovens, high-pressure containers, or on induction cookware.
5. In the event that the battery leaks and the fluid gets into one's eye(s), do not rub the eye(s). Rinse well with water and immediately seek medical care. If left untreated, the battery fluid could cause damage to the eye.

When CHARGING the Battery

WARNING

1. Be sure to follow the rules listed below while charging the battery. Failure to do so may cause the battery to become hot, rupture, or ignite and cause serious injury.
    - When charging the battery, either use a specified battery charger or otherwise ensure that the battery charging conditions specified are met.
    - Do not attach the batteries to a power supply plug or directly to a car's cigarette lighter.
    - Do not place the batteries in or near fire, or into direct sunlight. When the battery becomes hot, the built-in safety equipment is activated, preventing the battery from charging further, and heating the battery can destroy the safety equipment and can cause additional heating, breaking, or ignition of the battery.
2. Do not continue charging the battery if it does not recharge within the specified charging time. Doing so may cause the battery to become hot, rupture, or ignite.

CAUTION

The temperature range over which the battery can be charged is 0°C to 45°C. Charging the battery at temperatures outside of this range may cause the battery to become hot or to break. Charging the battery outside of this temperature range may also harm the performance of the battery or reduce the battery's life expectancy.

When DISCHARGING the Battery

WARNING

Do not discharge the battery using any device except for the specified device. When the battery is used in devices aside from the specified device it may damage the performance of the battery or reduce its life expectancy, and if the device causes an abnormal current to flow, it may cause the battery to become hot, rupture, or ignite and cause serious injury.

CAUTION

The temperature range over which the battery can be discharged is -20°C to 60°C. Use of the battery outside of this temperature range may damage the performance of the battery or may reduce its life expectancy.

APPENDIX C - ACCESSORIES

BIOLASE p/n	Description
2400040	Laser Safety Glasses (Clinician)
2400078	Laser Safety Glasses (Patient)
6400058	Remote Interlock Plug
2400129	Power Cord with Power Supply
6400522	Wireless Footswitch
6400311	Deep-Tissue Handpiece
6400310	Deep-Tissue Handpiece protective shields (qty. 20)
6400485	Peel-off clear screen covers (qty. 30)
6400457	Lithium ion battery pack for console
6400463	Battery Pack, (2 x AAA)
6400437	Trunk Fiber Assembly

APPENDIX E – ELECTROMAGNETIC COMPATIBILITY

CAUTION: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

Portable and mobile Radio Frequency (RF) communications equipment can affect medical electrical equipment.

Accessories: Medical grade power cord, maximum length 3ft (1 meter), Biolase p/n 2400043.

Footswitch: Wireless, Biolase p/n 6400522

WARNING: The use of accessories, other than those specified, except those supplied or sold by Biolase, Inc. as replacement parts for internal or external components, may result in increased EMMISSIONS or decreased IMMUNITY of the EPIC diode laser system.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The Epic diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Epic diode laser should assure it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	**Group 1**	The Epic diode laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	**Class A**	The Epic diode laser is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	**Class A**	
Voltage fluctuations/flicker emissions IEC 61000-3-3	**Class A**	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Epic diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the model Epic diode laser should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Continuous level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8kV air	± 6 kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 50%.
Electrical fast transient/burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines N/A	Main power quality should be that of a typical commercial or hospital environment. Input/output that does not apply because the footswitch cable length is less than 3 meters.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_r (>95% dip in UT) for 0.5 cycle 40% U_r (60% dip in UT) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles <5% Ur (>95% dip in U_r) for 5 seconds	<5% U_r (>95% dip in UT) for 0.5 cycle 40% U_r (60% dip in UT) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles <5% Ur (>95% dip in U_r) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Epic diode laser requires continued operation during power mains interruptions, it is recommended that the model Epic diode laser be powered from an uninterrupted power supply.
Power frequency (50-60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_r is the A.C. mains voltage prior to applications of the test level.			

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY *(Continued)*

The model Epic laser is intended for use in the electromagnetic environment specified below. The customer or the user of the model Epic laser should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Continuous level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150 kHz to 80 GHz 3V/m 80 MHz to 2.5 GHz	3 V 3Vm	Portable and mobile RF communications equipment should be used no closer to any part of the model Epic diode laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800MHz to 2.5GHZ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 8s the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 - At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Epic diode laser is used exceeds the applicable RF compliance level above, the Epic diode laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Epic diode laser.
B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE EPIC DIODE LASER

The Epic diode laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Epic diode laser can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Epic diode laser as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter M**		
	150kHz to 80Mhz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 – At 80 MHz and 800 MHZ, the separation distance for the higher frequency range applies.

NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

APPENDIX F - WIRELESS EQUIPMENT COMPLIANCE STATEMENT

This statement applies only to the wireless portion of the device:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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About BIOLASE

Founded in 1986, BIOLASE, Inc. specializes in lasers for medicine and dentistry that feature proprietary and patented technologies for minimally invasive surgeries, reducing pain and improving clinical results.

Only BIOLASE combines the leading laser technology – continuously improved through ongoing clinical R&D and engineering – with unmatched training, practice integration support and service.

BIOLASE leads the global dental laser market with over 21,000 lasers in use today and the most complete family of dental lasers – from diode lasers to the most advanced all-tissue laser, the WaterLase iPlus™.

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